

- (21) Application No. 51308/75 (22) Filed 15 Dec. 1975
(44) Complete Specification Published 8 Nov. 1978
(51) INT. CL.² A61F 5/01
(52) Index at Acceptance
A5R 6



(54) IMPROVEMENTS IN ORTHOPEDIC APPARATUS

(71) I, GLENN W. JOHNSON, JR., a citizen of the United States of America, of 10 Friar Tuck Circle, Summit, State of New Jersey, United States of America, do hereby declare the invention, for which I pray that a patent may be granted to me, and the method by which it is to be performed, to be particularly described in and by the following statement:-

The present invention relates generally to orthopaedic devices, and more particularly, to those orthopaedic devices known variously as casts, splints, braces etc., which are especially adapted for immobilizing and/or protecting injured limbs or other parts of the body.

It has long been desirable to replace the conventional plaster of paris cast with a device that among other advantages is light in weight, easily applied about an injured limb or other body part, reusable without being destroyed, and capable of periodic adjustment so as to conform to the changing size of the injured limb or other body part with which it is being used. One such device is disclosed, for example, in United Kingdom Patent 1,355,243 (Larson), and comprises a pair of rigid plastic shell members adapted to be releasably secured in enclosing relation about a damaged limb. Inside and extending coextensively with each rigid shell member there is disposed a flexible liner capable of being inflated by a suitable medium, say air, for example, introduced through a valve or inlet port to provide a constant pressure support means conforming to the irregular shape of the limb around which it engages. According to the teachings in the patent, by regulating the pressure within the inflatable liners suitable adjustment can be made to compensate for swelling and contraction of the damaged limb, or to achieve optimum body comfort for the wearer of the device.

While it is apparent that the device described in the aforementioned patent does offer considerable advantages over a conventional plaster cast, it still suffers from certain disadvantages.

For example, in the cast described in the Larson patent the two rigid half-shell members are releasably secured together along complementary abutting surfaces to form a hollow substantially cylindrical outer shell, the inside diameter of which is substantially greater than the largest outside diameter of the injured limb. Since each half-shell member includes a single inflatable liner, the damaged limb is directly supported by a two-part annular "air cushion" in the clearance space formed between the relatively regularly shaped interior of the cylindrical shell and the irregularly shaped surface contour of the injured limb. Even at relatively high inflation pressures, however, it is still possible for the damaged limb to move or be displaced relative to and within the outer shell notwithstanding the constant pressure support provided by the two inflated liners. The reason for this is that ideally, each inflated liner should form a dimensionally stable, relatively stiff "air-spring" which when compressed will offer increasing resistance to further displacement. However, the air cushions provided by the two inflated liners in the Larson cast being coextensive with each half-shell member respectively, are so relatively large in terms of their transverse and longitudinal extent that any loading of the inflated liner that is not directed substantially against the central portions thereof rather than being resisted by a firm compressive counterforce will merely displace air from one end of the liner to the other end of the same liner.

As a result, with respect to stresses imposed on the shell or the limb which might end to induce relative displacement of the limb in a direction parallel to and generally toward the longitudinally extending abutting surfaces of the two half-shell members, the inflated liners in the prior patented cast offer little or no pressure support or resistance against such displacement since it is along these seams that the extreme lateral extremities of the two liners abut each other.

Similarly, any stresses imposed on the limb or cast which would tend to rock the limb about a transverse axis perpendicular to the central longitudinal axis of the cast may cause the limb to "pinch" one or both of the inflated liners relative to the outer shell at say the upper extremity of the cast whereas at the bottom extremity of the cast the opposite side of the other or both liners would be similarly "pinched" thereby offering insufficient support against such rotational displacement of the limb relative to the cast's outer shell member.

The two-part annular air-cushion in the Larson device, therefore, actually comprises a relatively unstable floating suspension for the damaged limb which may not be completely effective in preventing undesirable displacements of the damaged limb relative to the cylindrical outer shell member encasing both the annular air-cushion and the limb.

Furthermore, as mentioned above, a significant feature of the prior art device is its ability to conform to the change in size of an injured limb. Such changes are typically contractions of the limb since the swelling attendant the original injury gradually subsides and as the period of immobilization continues the injured limb usually atrophies to an extent. It is apparent that since the inflatable liner is the only adjustable element in the prior art system the disadvantages described above with respect to the instability of the annular air-cushion between the outer shell and the injured limb is compounded when such adjustments are made inasmuch as the greater the annular thickness of the air-cushion between the encased limb and the outer protective shell, the greater is the freedom of and possibility for displacement of the limb relative to the outer shell.

Moreover, since the prior art cast of U.K. Patent No. 1,355,243 comprises a pair of rigid half-shell members defining a hollow cylindrical shell structure having a constant or fixed inside diameter once the device is assembled about an injured limb, the range of adjustment afforded thereby is extremely limited being dependent upon the degree which the inner liner can be extended radially under internal pressure and the maximum inflation pressure that can be tolerated by the wearer of the cast. This means that several different sized shells are required to treat corresponding damaged limbs of relatively disparate size and thus, for example, one size shell would be required to treat a damaged fibula on a small woman whereas a different sized shell member would be required to treat the same injury on a large male.

Against the foregoing background, it is a primary object of the present invention to provide an improved orthopaedic device which latter retains all of the advantages of the prior art device yet overcomes each of the disadvantages enumerated above.

According to one aspect of the invention,

there is provided an orthopaedic apparatus for immobilizing a body part including: a pair of complimentary half-shell members arranged to be fitted relative to each other about said body part in an opposed manner to define a tubular outer member surrounding said body part and generally conforming to the shape thereof,

said half-shell members being radially telescopically adjustable relative to each other about said body part whereby separate longitudinally spaced portions of the inner surface of each of said half-shell members may be caused to engage said part in an indirect abutting manner at corresponding longitudinally spaced locations along said body part respectively.

said half-shell members including means for releasably securing same together in a radially adjusted telescoped relation; and

a plurality of pneumatic inflatable cells disposed within said half-shell members in a circumferentially juxtaposed manner, said cells extending longitudinally with respect to said half-shell members and arranged to extend radially inwardly between the interior surface of said tubular outer member and said body part, whereby, in use, said apparatus may be radially telescopically adjusted to provide immobilizing support for said body part by means of said indirect abutting engagement and said pneumatic cells.

Apparatus and method according to the present invention will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1A is a perspective view of an embodiment of the invention, in particular, a walking cast suitable for treating an injured lower leg, showing the cast in unassembled condition;

Figure 1B is a perspective view showing the walking cast of Figure 1A in assembled condition, but not showing the cast in engagement with a lower leg;

Figure 2 is a sectional view in elevation showing the assembled cast of Figure 1B in engagement with a lower leg;

Figure 3 is a sectional plan view taken along line 3-3 of Figure 2;

Figure 4 is a sectional plan view taken along line 4-4 of Figure 2;

Figure 5 is a sectional plan view similar to Figure 3, but showing a slightly modified form of the cast shown in Figures 1A, 1B and 2-4;

Figure 6 is an enlarged detail view of a portion of Figure 3;

Figure 7 is a schematic side view in elevation of an alternative embodiment of the present invention, namely, a knee brace, showing the latter in engagement with a leg;

Figure 8 is a sectional plan view taken along line 8-8 in Figure 7;

Figure 9 is another sectional plan view taken along line 9-9 in Figure 7;

Figure 10 is a schematic side view in

70

75

80

85

90

95

100

105

110

115

120

125

130

elevation of another alternative embodiment of the present invention, in this case, a hinged knee brace, shown in engagement with a leg;

5 Figure 11 is a schematic front view in elevation of the hinged knee brace of Figure 10;

Figure 12 is a sectional view taken along line 12-12 of Figure 10; and

10 Figure 13 is a sectional plan view taken along line 13-13 of Figure 10.

Referring now to the drawings wherein like reference numerals represent like parts throughout, and initially to Figures 1-6, there is shown as illustrative of one form of the invention a walking cast generally indicated by reference numeral 10 and which is particularly adapted for treating injuries to the lower leg, e.g. medial fractures of the fibula or tibia.

15 Cast 10 comprises a pair of complementary, cooperating half-shell members 12, 14 each of which generally conforms to the shape of the foot and lower leg. Thus, each half-shell member essentially has a U-shaped or semi-cylindrical cross-sectional configuration and is generally formed in the shape of an "L" as shown in Figures 1A, 1B and 2. The vertically extending or upright portion 16 of shell member 14 conforms generally to the rear of the lower leg whereas the lower horizontally extending portion 18 of the shell member 14 conforms generally to the heel and sole portion of the foot. In similar fashion, the vertically extending or upright portion 20 of the half-shell member 12 generally conforms to the front of the lower leg while the lower horizontally extending portion 22 of the shell member 12 generally conforms to the upper or instep portion of the foot. If desired, half-shell members 12, 14 may have their inside diameters tapered slightly toward their bottom-most extremities to conform more closely to the shape of a typical lower leg while similarly, the vertically extending upright portion 16 of half-shell member 14 may be curved slightly in the longitudinal direction (i.e. in the plane of Figure 2) to conform more closely to the curve of the rear of the calf of the lower leg although this is not absolutely necessary as will appear obvious from the following description.

20 The individual half-shell members are fabricated from a thin material such that each half-shell member is extremely light in weight and moreover, has the capability of being easily flexed about its longitudinal axis to increase or decrease the inside diameter thereof while being relatively resistant to flexure about a transverse axis perpendicular to its longitudinal axis. While a wide range of known materials may be employed to meet the foregoing requirements, synthetic polymeric resinous materials such as the thermoplastics, for example, are particularly preferred since they are relatively inexpensive, are commercially available from several sources, and can easily be used to form the half-shell members in the shape substantially as shown in Figure 1A as by vacuum

forming, injection molding or other techniques well known in the plastics forming art. Exemplary thermoplastic materials suitable for use in practicing the present invention may be obtained commercially from Rhom and Haas Co. under the trademark KYDEX; General Electric Co., under the trademark LEXAN; Du Pont & Co., under the trademark LUCITE; and Borg-Warner Corporation under the trademark CYCOLAC.

70 It has been found that when the half-shell members 12, 14 shown in Figure 1A are formed from such materials having a thickness generally in the range of about .030 to about .100 inches, the half-shell members are easily flexed about their longitudinal axes respectively, are adequately rigid about a transverse axis perpendicular to said longitudinal axis and together weigh in the neighbourhood of about 1.5 to about 3.0 pounds.

75 In order to reduce still further the weight of the half-shell members 12, 14 they are each preferably provided with a plurality of spaced apart columns of apertures 24 substantially as shown in Figures 1A and 1B, the apertures in each column having a common centreline and being preferably equally spaced from one another so as to form a plurality of generally parallel spaced apart rows extending circumferentially with respect to each half-shell member. The apertures 24 comprising each row likewise are preferably equally spaced from one another, the spacing between apertures in each row, however, being generally greater than the spacing between apertures in each column. Since, as mentioned previously, the half-shell members may be tapered somewhat toward their lowermost extremities, respectively, under such circumstances, the various columns of apertures may be arranged in such a manner that the centrelines thereof slightly converge toward each other near the lower portion of each half-shell member. Thus, although the apertures in each row are equally spaced from one another, the spacing between apertures in the lowermost rows will generally decrease at a rate approximately equal to the rate of taper when compared to the spacing of the apertures in the rows disposed in the upper portion of each half-shell member. This arrangement has been found to produce an aesthetically appealing cast. In any event, the provision of a pattern of apertures 24 disposed on each shell member generally comprising a series of evenly spaced columns and rows as described above and as shown in the drawings has been found to reduce the weight of the individual half-shell members and at the same time improves the ability of the half-shell member to flex about its longitudinal axis while minimally affecting the ability of each half-shell member to resist flexure about a transverse axis perpendicular to said longitudinal axis. The reason for this may be more fully appreciated by observing that since the spacing between apertures in each row

is greater than the spacing between apertures in each column, the foregoing arrangement actually defines a series of spaced columns of necked-down flexural hinges 26, the columns extending circumferentially with respect to each half-shell member and each flexural hinge 26 having its bending axis parallel to the longitudinal axis of the half-shell member. The longitudinally aligned flexural hinges 26 thus permit each panel 28 defined between adjacent columns thereof to easily flex relative to its neighbouring panel about the shell member's bending axis while each panel 28 being arcuately shaped has considerable rigidity about a transverse axis perpendicular to its axis of curvature, that is, in effect it has the rigidity approaching that of a rigid column.

It is emphasized that the preferred arrangement of apertures 24 described above is not absolutely essential to assure the required degree of radial flexibility in each shell member 12, 14 since this may be accomplished merely by forming a sufficiently thin half-shell member. However, by using the preferred arrangement of apertures 24, half-shell members having increased thicknesses, relative to the thin material referred to above, may be employed thus assuring adequate rigidity about a transverse axis without affecting the desired ability of the shell member to be freely flexible about a longitudinal axis perpendicular to said transverse axis.

Moreover, as will be more fully explained below, the apertures 24 provided in each half-shell member 12, 14 are further advantageous in that they facilitate ventilation of the interior of the cast 10.

Half-shell member 12 has concentrically nested interiorly thereof a pneumatic cell or air bag 30 of generally flattened, arcuate configuration conforming to the inside curvature of the shell member. As best seen in Figure 2, the air bag 30 preferably extends substantially along the full vertical length of the half-shell member and includes an inlet tube or port 32 adapted to extend through one of the apertures 24 in the shell member 12 (see Figures 1A and 1B). The inlet tube or port 32 may be fitted with a valve or closure means of known construction for permitting the introduction of an inflating pressure into the interior of the air bag and for maintaining such internal pressure.

Likewise, half-shell member 14 has concentrically nested interiorly thereof a pair of similar air bags 30 extending in generally side-by-side spaced apart relation along virtually the full vertical extent of the half-shell member 14 (Figure 2) with each air bag including an inlet tube 32 adapted to extend through corresponding apertures 24 in the half-shell member 14.

Preferably, the transverse dimensions of the air bags 30 are slightly tapered toward the bottom of the cast 10 to conform more precisely to the similarly tapered contour of the

lower leg although this is by no means a necessity. It will be noted furthermore that the maximum lateral extent or dimension of each air bag 30 whether disposed within half-shell member 12 or 14 is substantially less than the transverse inside circumferential dimension of each half-shell member, respectively, or is substantially less than 180° of the transverse circumference of the limb with which it is intended to engage. The actual transverse extent of the individual air bags may vary depending upon the number used, however, when using three such air bags as indicated in Figures 1A, 1B, 3 and 4, each air bag preferably extends about 110° with respect to the transverse outer circumference of the limb (or 110° relative to the inner transverse circumference of the assembled cast 10), and is evenly spaced from the others, i.e. each air bag 30 has its centreline spaced approximately 120° from the corresponding centrelines of the other two neighbouring air bags.

The pneumatic cells or air bags 30 can be fabricated from any impervious thin, flexible material so as to be readily inflatable by a suitable medium such as air introduced through the inlet tube or port 32 thereby permitting the air bag to conform to the irregular shape or curvature of the injured limb with which each air cell is intended to engage as will be explained in further detail below. Thin vinyl plastics sheeting is an especially preferred material for the air bags 30 since such material may be cut and folded to shape quite easily and simply heat or ultrasonically sealed along the cut edges in a well-known manner. It will be appreciated, however, that other, thin, impervious, pliable materials such as rubber, coated fabrics etc., may be used as well.

As schematically indicated by the cross-hatched lines in Figures 1A, 1B and 2, each air bag 30 is preferably entirely encased in a jacket or sleeve 34 of soft absorbent material fabricated from a woven fabric, or if desired, from non-woven synthetic fibres. Other well-known materials may be employed as well provided they are pliable and are capable of absorbing moisture or the like. The sleeve or absorbent material provides a sterile surface in contact with the injured limb, helps to cushion the limb when encased within the half-shell members 12, 14, and furthermore facilitates ventilation of the contacted surface of the limb as will be explained more completely in the ensuing discussion.

It has been found that the air bags 30 need not be permanently affixed to the interior surfaces of the shell members 12, 14 but merely placed substantially in the position shown. This is advantageous in that the air bags may easily be replaced and furthermore may have their positions adjusted slightly to meet individual requirements. Of course, if desired, the air bags may be attached to the half-shell members by a light adhesive or other means as will occur to

those skilled in the art.

As mentioned above, the cast shown in Figures 1-6 is intended as a walking cast and towards this end, a rubber heel member 36 may be attached to the bottom generally flattened surface 38 of the lower horizontally extending foot portion 18 of the half-shell member 14 as best seen in Figure 2. The heel member 36 is preferably attached to the half-shell member 14 by a pair of threaded fastening elements 37 extending through suitably registering apertures in the half-shell member and heel member respectively. In order to provide comfort to the wearer of the cast, the shell member 14 includes a conventional resilient foot pad 40, whereas the shell member 12 includes a similar resilient pad 42 attached interiorly to the lower horizontally extending portion of the half-shell member and adapted to provide a cushion between this portion of the half-shell member 12 and the instep of the wearer's foot as is also shown in Figure 2. Resilient foot pads 40, 42 may readily be attached to their respective half-shell members by employing a suitable known adhesive.

For the purpose of releasably securing the half-shell members 12, 14 about an injured limb, closure means are provided preferably in the form of a series of circumferentially extending strips of flexible mating fastening material such as is commercially available under the trademark VELCRO. Half-shell member 14 includes a plurality of such strips 44 whose length is substantially greater than the circumferential extent of the shell member 14 itself. Each strip 44 of fastening material is attached to the exterior surface of the half-shell member 14 by a pair of diametrically opposed rivets 46 located inwardly from each lateral free edge 48 of the shell member 14, respectively, as seen to best advantage in Figure 6. Each VELCRO fastening strip 44 on the half-shell member 14 thus includes a pair of ends 50, 52 adapted to freely extend beyond the lateral free edges of the shell member 14 (Figure 1A). Half-shell member 12 carries a corresponding plurality of circumferentially extending complementary VELCRO fastening strips 54 attached to the exterior surface thereof by similar rivet means 56 (see Figure 6). The circumferential extent of the fastening strips 54 is less than that of the half-shell member 12 and the extremity of each strip 54 terminates at a point displaced inwardly from the free lateral edge 58 of the half-shell member 12 as depicted in Figure 6. As shown in Figures 1A and 1B, there are three fastening strips 44 located at regularly spaced intervals along the vertical or upright portion of the half-shell member 14 and a fourth such strip 44 located on the lower horizontally extending foot portion 18 of the half-shell member 14. It will be noted that the latter fastening strip extends through a slot 60 formed in the heel member 36 between the latter and the lower surface 38 of the

horizontally extending foot portion of half-shell member 14 and thus serves to maintain this fastening strip in its intended position (see Figure 2). Similarly, half-shell member 12 has four fastening strips 54 located in such a manner as to be circumferentially aligned with the fastening strips 44 on the half-shell member 14 when the two half-shell members are in assembled condition as indicated in Figure 1B. Although four fastening strips are employed in connection with the walking cast of Figures 1-6, it will be appreciated that this number is not critical and may be varied depending upon the size and type of cast being utilized. Suffice it to say, that a sufficient number of strips are employed at spaced apart distances longitudinally with respect to the cast to prevent buckling of either half-shell member when the two half-shell members are assembled relative to each other and an injured limb as will be explained below.

In accordance with the present invention, the walking cast 10 may easily be applied about an injured limb — in the case illustrated the lower leg — by simply placing the limb in the half-shell member 14 as shown in Figure 2 with the sole of the foot resting on resilient pad 40 and with the back of the heel and the rear portion of the mid-calf in snug abutting contact with the non-inflated air bags 30 at the areas indicated, for example, by the letters *a* and *b* (see also Figure 4).

Half-shell member 12 is then held in the position shown in Figure 1A and fitted relative to the half-shell member 14 by engaging the latter about the injured limb in a radially telescoping manner. That is, the diametrically opposed lateral free edge portions 58 of the half-shell member 12 are flexed slightly outwardly to permit them to overlap and receivably engage the corresponding diametrically opposed lateral free edge portions 48 of the half-shell member 14 with the half-shell member 12 being displaced relative to the half-shell member 14 generally in the direction indicated by arrow 60 in Figure 6. Such displacement causes the inner surface 62 adjacent each lateral free edge portion 58 of the half-shell member 12 to slide relative to the juxtaposed outer surface 64 adjacent each lateral free edge portion 48 of the half-shell member 14 with the two sliding surfaces in light frictional engagement with one another. The half-shell member 12 is so displaced relative to the half-shell member 14 and the injured limb until the half-shell member 12 assumes the position substantially as shown in Figure 2 at which position the front or shin bone portion of the leg in the proximity of the mid-calf and the instep of the foot are in snug abutting contact with the flattened air bag 30 and the resilient foot pad 42 as indicated by the letters *c* and *d*, respectively, and these parts, in turn, are in abutting contact with the interior surface of the shell member 12. Of course it

will be appreciated that due to the irregular shape of the lower leg and the relatively regular shape of the half-shell members 12, 14 direct abutting contact between the leg and the interior surface defined by the inwardly facing portions of the non-inflated, flattened air bags 30 will not occur at several locations within the assembled cast, for example, around portions of the ankle and below and above the mid-calf.

There will be indirect abutting engagement between the lower leg and the two radially telescoped half-shell members at least at two longitudinally spaced locations along the leg as, for example, generally indicated by the letters *a* and *c* in Figure 4, and preferably at two spaced circumferential locations as, for example, generally indicated by the letters *a* and *d* on the one hand and *b* and *c* on the other hand in Figure 2 with the two longitudinally spaced locations of snug indirect abutting engagement with the radially telescoped half-shell members preferably straddling the injured portion of the limb. Fulfillment of this requirement is facilitated by the fact that the two half-shell members have the capability of easily being flexed about their central longitudinal axes and therefore are capable of being radially telescoped with respect to each other as mentioned above, and thus the inner diameter of the radially telescoped, substantially cylindrical shell structure formed by the two diametrically opposed nested half-shell members can readily be selectively adjusted with respect to the limb so as to achieve the aforescribed indirect abutting engagement independent of the size or irregular shape of the limb.

As used herein the term "indirect abutting engagement" of the body part, means by way of an intermediate layer or layers of material other than fluid, for example, portions of the pneumatic cells in flattened condition.

As used herein, the term "radially telescoped" means to adjust telescopically in a transverse direction relative to the longitudinal axis of the body part to which the orthopaedic apparatus is to be applied.

It will be understood that the term "radially telescoped" as used herein and in the appended claims refers broadly to the situation where the pair of half-shell members are placed in diametrically opposed facing position relative to each other and are nested relative to each other about a limb or other body part to form a substantially annular shaped hollow structure. Due to the flexibility of the half-shell members the internal diameter of the resulting annular shaped structure may be selectively adjusted by flexing the two half-shell members and simultaneously radially displacing the half-shell members relative to each other and the encased limb. The term "radially telescoped" is thus to be distinguished from the meaning usually ascribed to the term "telescoped" which implies the nesting of an annular member of a

given diameter within another annular member of a greater diameter by the longitudinal or axial displacement of the first mentioned annular member relative to the second mentioned annular member or vice versa.

Half-shell members of a single standard size can be employed and adjusted by radially telescoping the members, by flexing and relatively displacing the members to fit a wide range of varying sized corresponding limbs, or can be adjusted from time to time during the period of immobilization to conform to the changing size of a particular limb, the range of adjustment depending only upon the extent to which the lateral free edge portions of each half-shell member may be flexed and surface 62 on each lateral portion of the half-shell member 12 is permitted to slide relative to the other half-shell member's corresponding surface 64 in the direction of the arrow 65.

When the two half-shell members 12, 14 are engaged with each other in a radially telescoping manner and are in indirect abutting engagement with the injured limb at the preferred spaced apart longitudinal locations with respect to the injured limb as described above, the half-shell members 12, 14 may be fixed in position relative to each other and the encased limb by attaching the freely extending ends 50, 52 of the VELCRO fastening strips 44 on half-shell member 14 to the corresponding VELCRO fastening strips 54 on the half-shell member 12 as substantially shown in Figures 1B, and 3-6. The resulting radially telescoped shell structure so formed will provide a protective casing or column circumscribing the injured limb that inherently is extremely rigid about a transverse axis perpendicular to the longitudinal axis of the casing, and as explained above will be in indirect abutting engagement with the injured limb at at least two axially or longitudinally displaced locations thereby preventing relative displacement of the injured limb with respect to the radially telescoped shell structure or protective casing.

In passing it will be noted that the flexed diametrically opposed lateral portions of each half-shell member 12, 14 will tend to return to their normal unflexed positions and this condition will produce a biasing or spring-force in the radial direction sufficient to maintain a firm frictional engagement between the corresponding overlapping engaged surfaces of the two half-shell members (Figure 6). This frictional gripping engagement, in turn, helps to maintain the two cooperatively engaged half-shell members in their adjusted relative position during engagement of fastening strips 44, 54 and moreover, is helpful in preventing relative displacement of the two engaged half-shell members in a direction parallel to the longitudinal axis of the shell structure (i.e. in a direction normal to the plane of the paper as viewed in Figure 6) after the fastening strips 44, 54 have been engaged and the shell structure

fitted about the injured limb.

After the half-shell members 12, 14 has been assembled as shown in Figure 1B, and as described above, air or other suitable inflation medium is then introduced into each air bag 30 through their respective inlet tubes 32 to cause the air bags to inflate. Sufficient internal pressure is developed in each air bag to completely fill the annular spaces or voids existing between the inwardly facing sides or portions of the air bags and the relatively irregularly contoured surface of the injured limb as shown, for example, in Figures 2 and 3. Inflation of the flexible air bags 30 causes them to conform to the portions of the limb not in indirect abutting engagement with the interior surface of the shell structure and thereby provides firm constant pressure support for these portions of the limb. In addition, such inflation renders the outer radially telescoped shell structure extremely rigid with respect to further flexural displacement about the shell structure's longitudinal axis. Since each air bag 30 has a relatively small interior volume, and the air bags are confined between the outer shell structure and the encased limb, relatively low inflation pressures ranging from about 15 to about 25 mm. Hg. have been found to provide unexpectedly firm support. Thus, by employing as few as three air bags at spaced intervals about the circumference of the limb as indicated in Figure 3, a three-point suspension may be achieved capable of completely immobilizing an injured limb encased within the radially telescoped shell structure.

Moreover, it will be noted in accordance with an important feature of the present invention that despite inflation of the air bags 30 as described above, the portions of the immobilized limb originally in indirect abutting engagement with the interior of the telescoped shell structure will virtually retain their indirect abutting engagement with the interior surface of the two radially telescoped half-shell members. This is shown to best advantage in Figure 4, for example, at locations indicated by the letters b and c. In contrast, the inflated air bags do extend radially to fill the voids between those portions of the limb not in indirect abutting engagement with the interior of the radially telescoped shell structure as clearly shown in Figures 2-4. Since, as mentioned above, the immobilized limb always remains in virtual indirect abutting engagement with the interior surface of the cylindrical shell structure formed by the two radially telescoped half-shell members 12, 14 at two longitudinally spaced locations, the damaged limb is prevented from being moved or displaced relative to or within the shell structure and thus, in effect, the cylindrical shell structure itself as well as the circumferential array of air cushions provided by the inflated air bags 30 contribute to immobilization of the injured limb, whereas heretofore prior art casts of the type described

herein have depended only upon an annular air cushion to effect such immobilization.

Furthermore, by providing more than two air cells where each air cell or air bag 30 has a transverse dimension substantially less than the inside circumferential dimension of each half-shell member respectively (or extending over substantially less than 180° of the circumference of the injured limb) as shown in Figure 3, for example, the lateral extremities of the inflated air cells as well as their central portions have been found to be relatively dimensionally stable in response to radially applied compressive loads imposed thereon by the injured limb thereby contributing toward the excellent stability of the immobilized limb within the radially telescoped outer structure especially with regard to preventing lateral displacements of the limb relative to the outer shell.

Similarly, it will be understood that the action of maintaining the radially telescoped half-shell members in indirect abutting engagement with the injured limb after inflation of the air bags 30 serves to maintain each inflated air cell dimensionally stable with respect to its longitudinal or axial extent and thus effectively prevents relative rotational displacement of the limb about a transverse axis perpendicular to the longitudinal axis of the outer shell structure.

As previously explained, the preferred arrangement of three air bags 30 nested within the radially telescoped shell structure in circumferentially spaced apart relationship as depicted in Figures 3 and 4 is further advantageous in that it permits placement of the individual air bags 30 to be adjustably varied relative to one another to assure optimum comfort to the wearer of the cast. In addition, the apertures 24 in the half-shell members 12, 14 permit unimpeded circulation of air into the interior of the cast and into direct contact with the limb's skin surface exposed between the spaced apart air bags. This permits the skin to breathe freely reducing surface heat and perspiration, and in general, further enhances the wearer's comfort. Nonetheless, it may be desirable especially during the early stages of immobilization when edema due to the original injury is present, to completely surround the injured limb with a constant pressure supporting surface in engagement therewith. Accordingly, as shown in Figure 5, an additional air bag 30 may be placed in nesting position within the shell structure formed by the two interengaging radially telescoping half-shell members and the four air bags embedded such that the lateral edge of each air bag slightly overlaps the adjacent lateral edge of its neighbouring air bags. By this alternatively preferred arrangement the entire annular space between the interior surface of the encased limb is occupied by the overlapping air bags and a multi-cellular constant pressure supporting surface is provided

completely surrounding and engaging the injured limb. Of course, it will be appreciated in connection with Figure 5 that as in the case where only three air bags are provided in circumferentially juxtaposed position (Figure 3), at least two longitudinally spaced portions of the injured limb still will virtually remain in indirect abutting engagement with the interior wall surface of the shell structure as indicated, for example, by the letters *a*, *b*, *c* and *d* in Figure 2 and the letters *b* and *c* in Figure 4.

It will be recalled that each individual air bag 30 includes an outer sleeve or covering 34 of absorbitive material. Referring to Figure 6, the manner in which such absorbitive outer sleeve in conjunction with the apertures 24 provided in each half-shell member 12, 14 function to afford excellent ventilation of the interior of the cast will now be explained. As clearly shown in Figure 6, inflation of each air bag 30 causes the laterally inwardly facing portion 66 of its corresponding outer sleeve 34 to directly engage in conforming relation a coextensive portion of the exterior skin surface 68 of the immobilized limb. Since the inwardly facing portion 66 of the air bag's absorbitive outer sleeve is quite firmly urged against the skin surface 68 owing to the internal pressure of the air bag, normal body heat is prevented from being transferred away from that portion of the skin surface 68 in contact with the air bag's outer absorbitive sleeve. As a result normal evaporative cooling is prevented and liquid perspiration rapidly collects and remains trapped between the air bag outer sleeve and the surface of the limb with which it is in contact. Unless removed such trapped perspiration can eventually cause irritation of the skin and/or discomfort to the wearer of the cast. The provision of an absorbitive liner on the inner surface of the inflatable air bag may be effective to absorb such perspiration. However, it has been found that when the absorbitive liner extends only along the inner surface of the inflatable air bag, it quickly becomes saturated and can no longer absorb any further perspiration which because of natural body processes is continuously being produced. In contrast, it will be observed in Figure 6 that the absorbitive sleeve 34 contemplated by the present invention not only extends along the inwardly facing surface 70 of each air bag but completely surrounds the air bag and thus extends along the outwardly facing surface 72 of the air bag as well. Due to this arrangement, the outwardly facing portion 74 of the absorbitive sleeve on each air bag is directly disposed in juxtaposed relation with regard to the apertures 24 in either half-shell members 12 or 14 as the case may be. Hence, the liquid perspiration absorbed by the inwardly facing portion 66 of the sleeve 34 is urged to flow, by wicking action along the directions indicated by arrow 76 into the region of the outwardly facing portion 74 of the sleeve 34 where it is

easily evaporated off due to the latter portion of the protective sleeve being in direct proximity to the apertures 24. In effect, therefore, by providing a sleeve 34 of absorbitive material completely encircling each air bag 30 as shown in Figure 6, an uninterrupted flow path is provided for continuously transferring liquid perspiration from the portion of the skin surface 68 engaged by each air bag outer sleeve to the vicinity of the apertures 24 where the perspiration is evaporated off thereby preventing its accumulation and consequent irritation of the skin surface and/or discomfort to the wearer of the cast.

Although the walking cast described above is intended to protect and immobilize the foot and the lower leg up to a point immediately below the knee, it may obviously be modified to extend above the knee, i.e. beyond the lower leg. Nor is the invention to be limited exclusively to walking casts as such. Thus, cast 10 may with only slight modification and without departing from the invention be adapted for the treatment of limbs or other parts of the body such as the lower arm, the upper arm, the upper thigh, and so on.

Moreover, orthopaedic devices constructed in accordance with the present invention may be applied to the treatment of damaged or injured joints interconnecting a pair of limbs or other body parts. To illustrate this, a further modified form of the invention intended for immobilizing a damaged or injured joint interconnecting a pair of articulated limbs or body members will now be described in connection with Figures 7-9, in particular, a knee brace for immobilizing a damaged knee joint connecting the thigh and lower leg.

As schematically shown in Figures 7 to 9, the knee brace 110 comprises a pair of complementary, interengaging half-shell members 112, 114, each generally having a U-shaped or semi-cylindrical cross-sectional configuration for conforming to the lower portion of the thigh and the upper portion of the lower leg. Since the cross-sectional dimension of the thigh at the location engaged by the upper extremities of the two shell members 112, 114 is usually appreciably greater than the cross-sectional dimension of the calf engaged by the lower extremities of the two half-shell members, the latter are preferably formed having a gradual reduction in their inside diameter as the lower end is approached, i.e. from a maximum at their upper extremities to a minimum at their lower extremities. Additionally, for increased comfort, the two half-shell members 112, 114 are preferably slightly longitudinally curved substantially at their mid-sections respectively to accommodate the leg in a slightly flexed condition as indicated in Figure 7.

Nested interiorly within the knee brace formed by the interengaging half-shell members 112, 114 is a pair of flattened arcuately

extending air cells or air bags 116 each preferably having a valved inlet port communicating with the exterior of the shell member 114 through a suitable aperture provided therein (not shown). Air bags 116 are preferably positioned in a diametrically opposed manner along the lateral portions of the leg engaged by the knee brace as best seen in Figure 8 with each air bag extending longitudinally along the interior surface of the knee brace from a position above the knee to a position below the knee as shown in Figure 7. In order to improve the stability of each air cell or bag 116 when inflated, the longitudinal dimensions thereof are substantially less than the longitudinal dimension of each half-shell member 112, 114; and in particular, are preferably about one-half the longitudinal extent of each half-shell member. To conform to the gradual taper of the two shell members 112, 114, each air bag 116 preferably is gradually tapered from a maximum transverse dimension at the upper extremity thereof above the knee to a minimum transverse dimension at the lower extremity thereof below the knee as is also generally indicated in Figure 7. In addition, the transverse dimension of each air cell 116 measured along any given transverse plane is substantially less than the transverse inside circumference of each half-shell member respectively, and preferably is adapted to extent about 110° with respect to the transverse outer circumference of the limb at the axial location defined by said given transverse plane. When inflated, the air bags are adapted to extend radially so as to fill the voids between the sides of the leg and the interior of the knee brace formed by interengagement of the two half-shell members as indicated in Figure 8 and as will be described below.

A pad 120 preferably of resilient sponge rubber or the like material is affixed to the interior of the half-shell member 112 by suitable adhesive means in position to abut and directly engage the front portion of the leg immediately above the knee cap as depicted in Figures 7 and 8. The sponge rubber pad 120 helps to maintain the leg in a fixed position within the knee brace and prevent motion of the knee relative to and within the brace. Alternatively, an air bag (not shown) of substantially the same size and shape as the resilient sponge rubber pad 120 may be used instead.

For additional comfort, each half-shell member 112, 114 may be provided with an arcuately shaped cuff member 122 of similar sponge rubber material fixed interiorly thereof at either extremity as shown in Figures 7 and 9 since it is at these locations that the interior of half-shell members 112, 114 are in snug abutting peripheral contact with the thigh and lower leg, respectively. Here again, however, air bags (not shown) of substantially the same size and shape may be used in place of the resilient

sponge rubber cuff members 122.

A plurality of cooperatively engaging VELCRO fastening strips 44, 54 as described above in connection with the walking cast of Figures 1-6 may be employed in the manner indicated in Figures 7-9 to releasably secure the half-shell members 112, 114 in relative engaged position about the encased leg. Of course, it will further be appreciated that each half-shell member 112, 114 may, if desired, also include the aperture 24 and similarly, the absorbitive sleeve 34 surrounding each air bag 116, although these parts have not been shown in Figures 7-9 for the sake of brevity.

Moreover, half-shell members 112, 114 are preferably formed of the same tough, thin, flexible material as are the previously described half-shell members 12, 14 and thus are adapted to be fitted about the leg in substantially the same manner. That is, initially the uninflated, flattened air bags 116 are disposed in their preferred diametrically opposed, lateral positions relative to the leg as shown, for example, in Figures 7 and 8. Half-shell member 112 is then positioned diametrically opposite to half-shell member 114 and displaced relative to the latter and the leg for engagement therewith in a radially telescoping manner, i.e. the free lateral edge portions of half-shell member 112 are flexed outwardly for receivably engaging the free lateral edge portions of shell member 114, and the corresponding lateral edge portions of the shell members 114, 112 are slid relative to each other in overlapping frictional engagement until the two resilient arcuate cuff members 122 and the resilient pad 120 on the half-shell member 112 snugly and firmly engage the leg.

The two-shell members 112, 114 are then fastened relative to one another and the encased leg by attaching the freely extending portions of the VELCRO fastening strips 44 carried by the half-shell member 114 to the circumferentially aligned VELCRO fastening strips 54 located on shell member 112 substantially as shown in Figures 7-9. Finally, the air bags 116 are inflated to provide a pair of constant pressure supporting surfaces on either side of the knee (and above and below the knee) which in conjunction with the resilient cuffs 122, and the resilient pad 120 engaging the front of the leg immediately above the knee cap, firmly lock the thigh and lower leg in the slightly flexed condition shown in Figure 7. Hence the thigh is prevented from moving relative to the lower leg and vice versa, and the damaged or injured knee joint interconnecting these articulated body members is completely immobilized.

It is frequently desirable to provide a brace for an articulated limb wherein the brace is effective to permit controlled relative motion between the limb portions about the natural axis of the joint connecting them, and at the same time limit or prevent relative motion

between the limb portions about a transverse axis perpendicular to the joint's natural axis. The foregoing is readily achieved in accordance with still another form of the present invention which will now be described with reference to Figures 10-13. As schematically shown in the latter, the half-shell members of a first pair 210, 212 are radially telescopically engaged with one another about the upper portion of a lower leg at a position immediately below the knee. Likewise, a second pair of half-shell members 214, 216 is radially telescopically engaged about the lower portion of the thigh connected to the lower leg at a position immediately above the knee. Nested interiorly within each half-shell member 212, 216 is an inflatable air bag 218 whereas nested interiorly within each half-shell member 210, 214 is a thin pad of resilient sponge rubber 220 or the like substantially as indicated in Figures 10 and 13. If desired, an inflatable air bag 218 may be used in conjunction with all of said half-shell members 210, 212, 214, 216 or a resilient sponge rubber pad 220 or the like may be used in conjunction with all of these half-shell members. The individual pairs of half-shell members 210, 212 and 214, 216 are releasably fastened together respectively in the position shown by means of the previously described circumferentially aligned, engaging VELCRO fastening strips 44, 54. It will thus be appreciated that the two longitudinally spaced pairs of cooperatively engaged half-shell members 210, 212 and 214, 216 define respectively, a lower and upper brace member which upon engagement of the fastening strips 44, 54 and inflation of the air bags 218 are firmly and snugly fixed about the lower leg and thigh respectively, on either side of the knee joint in essentially the same manner the previously described walking cast (Figures 1-6) and knee brace (Figures 7-9) are firmly and snugly fixed about their respective body parts.

Half-shell member 212 carries a pair of diametrically opposed longitudinal strut members 221, 222 positioned substantially adjacent each lateral free edge of the half-shell member respectively and extending upwardly therefrom on either side of the knee joint in a generally parallel manner with respect to the half-shell member's longitudinal axis. The strut members 221, 222 are removably rigidly attached to the half-shell member 212 by a pair of conventional threaded fastener elements 224 extending through corresponding registering spaced apart apertures in the strut members 221, 222 and the half-shell member, respectively. Whereas only two apertures are provided in the strut members 221, 222 a plurality of longitudinally aligned apertures 226 in excess of two are provided in each lateral free edge portion of the shell member and are adapted to be engagable by the threaded fastening elements 224 so that the height to which each strut member 221, 222 extends beyond the upper edge 228 of shell member 212 may be

adjusted merely by selecting different corresponding pairs of said apertures 226 in the shell member for engagement with the threaded fastening elements 224 extending through the two spaced apertures provided in each strut member, 221, 222.

It will be noted in Figure 11 that strut member 221 includes a laterally offset portion substantially intermediately thereof. This is to provide sufficient clearance space between this strut member and the normally outwardly bulging inside portion of the knee.

Half-shell member 216 carries a corresponding pair of diametrically opposed longitudinal strut members 230, 232 also positioned substantially adjacent each lateral free edge portion of the half-shell member respectively, and extending downwardly therefrom on either side of the knee joint and generally parallel to the longitudinal axis of the half-shell member. Strut members 230, 232 are removably rigidly attached to half-shell member 216 by a pair of the threaded fastening elements 224 extending through corresponding registering spaced apart apertures in the strut members 230, 232 and the half-shell member respectively.

As shown in Figures 10 and 11, the downwardly extending strut members 230, 232 carried by half-shell member 216 are respectively rotatably connected to the upwardly extending strut members 221, 222 carried by half-shell member 212 along a common hinge axis 236 by a pair of pin connections generally represented by reference numerals 240, 242.

Since pin connections 240 and 242 are identical, a description of one will suffice for the other. Thus, referring to Figure 12, strut members 230, 221 each have corresponding apertures 244, 246 of substantially equal diameter disposed in their distal end portions respectively, and through which the axle portion 248 of the connecting pin 240 is adapted to be loosely received. The pin 240 includes a flanged head portion 250 bearing lightly against the side of strut member 221 and has a terminal portion 252 of stepped-down or reduced diameter relative to its axle portion 248 to define a bearing shoulder 254. A flanged retaining disc 256 has a central bore 258 sized to enable the disc to be received on the reduced diameter terminal portion 252 in abutting relation with respect to shoulder 254. A fastening element 260 threaded axially into pin 240 and a washer 262 fixedly retain the disc 256 in abutting relation against the shoulder 254. Since the axial extent of axle portion 248 is slightly greater than the combined thickness of strut members 230, 221, the latter are coupled together by connecting pin 240 but are free to rotate relative to each other about the pin's axis 264 which, of course, corresponds to the common hinge axis 236. In the same manner strut members 232, 222 are connected together by a pin 242 and are free to rotate relative to each other about axis 236.

When the common hinge axis 236 is adjusted to substantially coincide with the natural hinge axis of the knee joint around which the upper and lower brace members are fitted, it becomes readily apparent that the hinged knee brace of Figures 10-13 is capable of permitting normal relative motion of the lower leg relative to the thigh. However, by virtue of the interconnected strut members 230, 221 and 232, 222 which are disposed on either side of the knee joint respectively in substantially perpendicular relation to the knee joint's natural hinge axis, the hinged knee brace effectively immobilizes the knee joint against torsional or twisting movements about any transverse axis 270 perpendicular to hinge axis 236 and this is especially effective in preventing lateral extensions of either the thigh or lower leg.

In the event it is desired to limit the normal extension of the knee joint about the hinge axis 236, means may be provided in the form of a limit stop 274 attached to each strut member 221, 222 by a threaded fastener 224 as shown in Figures 10 and 12, the limit stop being adapted to cooperate with surface 276 provided on the distal end portions of each strut member 230, 232.

While particular preferred embodiments of the present invention have been disclosed hereinabove, many modifications within the scope of the invention may be made. For example, instead of utilizing an inflatable pneumatic cell or air bag that includes an inlet port and/or valve means through which a pressurizing medium may be admitted after the radially telescoped half-shell members have been fitted about a body part, it is anticipated that a completely sealed air bag inflated to a pre-determined internal pressure prior to such installation may be used alternatively although this may require slightly more skill and care when fitting the half-shell members about the injured body part. Similarly, instead of using fastening strip members fabricated from VELCRO fastening material, other conventional fastening devices may be employed to releasably secure the half-shell members together such as, for example, belt and belt buckles, adhesive tape and so on.

WHAT I CLAIM IS:-

1. Orthopedic apparatus for immobilizing a body part including: a pair of complimentary half-shell members arranged to be fitted relative to each other about said body part in an opposed manner to define a tubular outer member surrounding said body part and generally conforming to the shape thereof.

said half-shell members being radially telescopically adjustable relative to each other about said body part whereby separate longitudinally spaced portions of the inner surface of each of said half-shell members may be caused to engage said part in an indirect abutting manner at corresponding longitudinally spaced locations along said body part

respectively.

said half-shell members including means for releasably securing same together in a radially adjusted telescoped relation; and

a plurality of pneumatic inflatable cells disposed within said half-shell members in a circumferentially juxtaposed manner, said cells extending longitudinally with respect to said half-shell members and arranged to extend radially inwardly between the interior surface of said tubular outer member and said body part, whereby, in use, said apparatus may be radially telescopically adjusted to provide immobilizing support for said body part by means of said indirect abutting engagement and said pneumatic cells.

2. Apparatus according to claim 1 wherein said body part comprises the lower leg and foot of a human, one of said half-shell members being L-shaped to generally conform to the back of the lower leg and underlie the heel and sole of the foot, the other of said half-shell members being L-shaped to conform generally to the front of the lower leg and overlie the instep portion of the foot, and wherein the inner surface of said one half-shell member is intended in use to engage said body part at separate longitudinally spaced locations in an abutting manner including the back of the lower leg and the heel and the sole of the foot, and the inner surface of said other half-shell member is intended in use to engage said body part at separate longitudinally spaced locations in an abutting manner including the front of the lower leg and the instep of the foot whereby said orthopaedic apparatus is employable as a walking cast.

3. Apparatus according to claim 1 or 2 wherein said means for releasably securing said half-shell members together comprises a plurality of fastening members longitudinally spaced along the outer surfaces of said tubular outer member, each of said fastening members including a first flexible fastening strip affixed exteriorly to one half-shell member and a second flexible fastening strip affixed exteriorly to the other half-shell member in circumferential alignment with said first fastening strip, said first fastening strip having a pair of end portions respectively extending beyond the radially spaced free edges of said one half-shell member, said second fastening strip having a pair of end portions terminating respectively in spaced relation with respect to the radially spaced free edges of said other half-shell member respectively, said end portions of said first fastening strip being placed in fastening mating engagement with said terminal end portions of said second fastening strip, respectively, when said half-shell members are secured together in said adjusted radially telescoped relation about said body part.

4. Apparatus according to any preceding claim wherein each of said plurality of cells comprises an inflatable flexible bag including

valve means for permitting a pressurizing medium to be introduced therein for maintaining said pressurizing medium within said inflatable bag at a desired internal pressure.

5 5. Apparatus according to any preceding claim wherein said plurality of cells comprises three in number, and said cells are disposed within said tubular outer member in circumferentially spaced relation from one another.

10 6. Apparatus according to any one of claims 1 to 5 wherein said plurality of cells comprises four in number, said cells being disposed within said tubular outer member such that the opposed lateral extremities of each cell respectively slightly overlap a lateral extremity of a neighbouring cell to define a multi-cellular supporting surface adapted to completely circumferentially surround said body part.

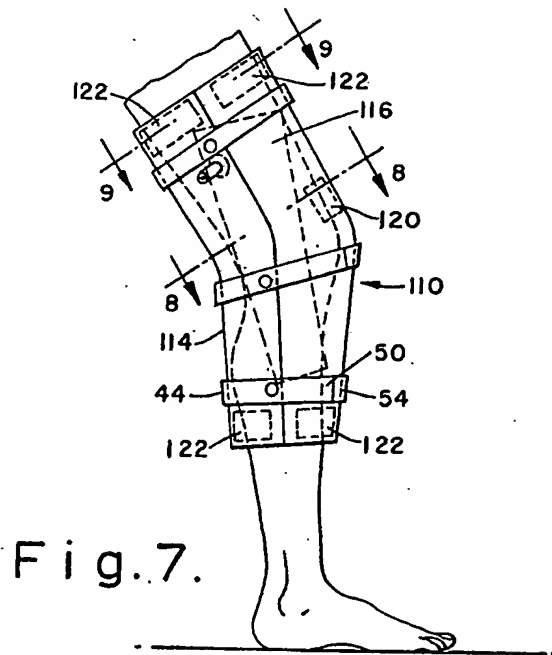
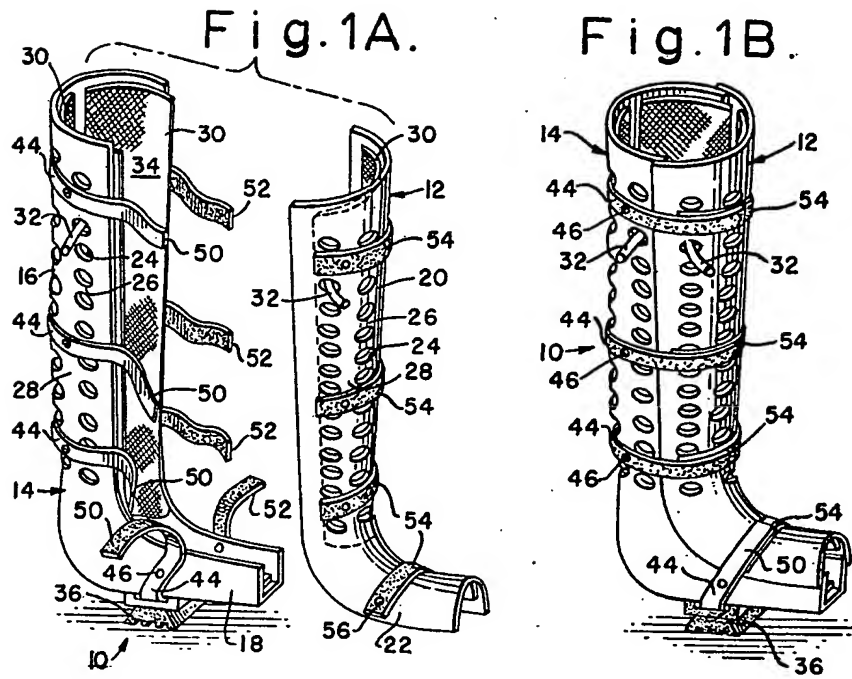
15 7. Apparatus according to any one of claims 1 to 5 wherein said plurality of cells comprises two in number, said cells being disposed within said tubular outer member in a diametrically opposed manner between the diametrically opposed seams of said tubular outer member and the outer surface of said body part respectively, said seams being defined by the overlap between the free edges of said half-shell members.

20 8. Apparatus according to claim 4

wherein at least one of said flexible bags includes an outer sleeve of absorbent material extending substantially completely circumferentially around said one bag, a circumferential portion of said outer sleeve contacting the inner surface of said tubular outer member so that a circumferential corresponding portion of said outer sleeve is capable, in use, of contacting the surface of said body part, each of said half-shell members being provided with a plurality of spaced apertures, said circumferentially corresponding portion of said outer sleeve being in registration with at least some of said spaced apertures whereby perspiration on said surface of said body part may be absorbed by said outer sleeve and caused to wick to said circumferentially corresponding portion of said outer sleeve and be evaporated off through said apertures in registration therewith.

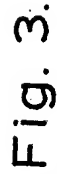
9. Apparatus according to claim 1 substantially as hereinbefore described with reference to the accompanying drawings.

LANGNER PARRY,
Chartered Patent Agents,
High Holborn House,
52-54 High Holborn,
London WC1V 6RR
Agents for the Applicant



This drawing is a reproduction of
the Original on a reduced scale.

SHEET 2



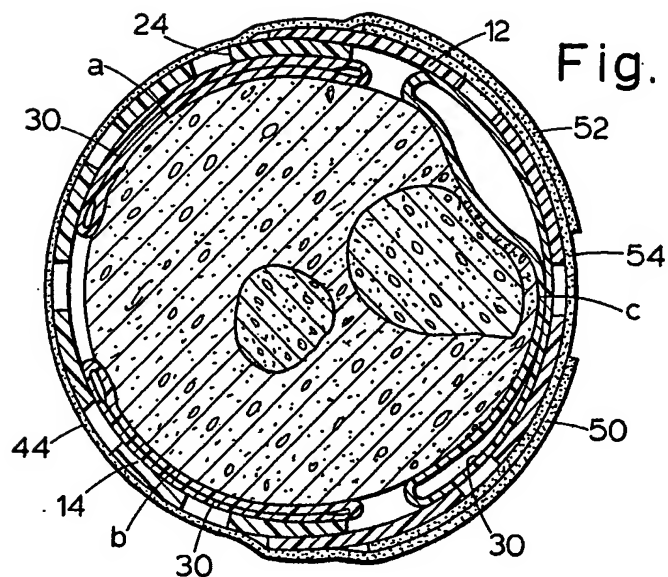


Fig. 4.

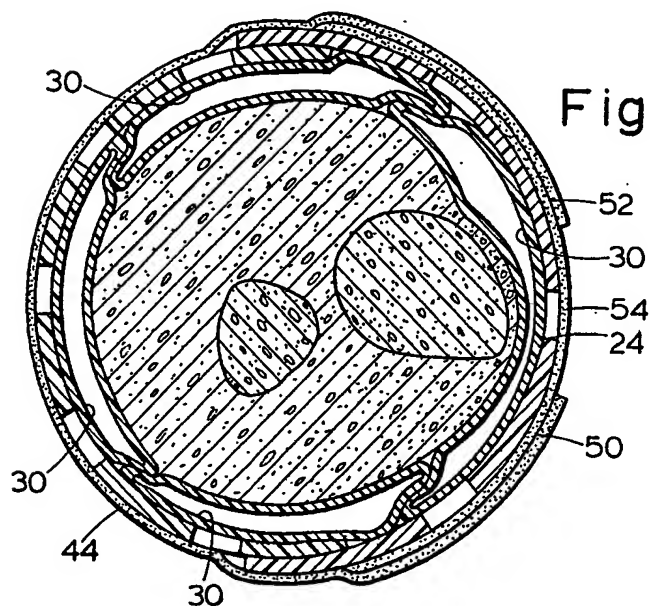


Fig. 5.

Fig. 8.

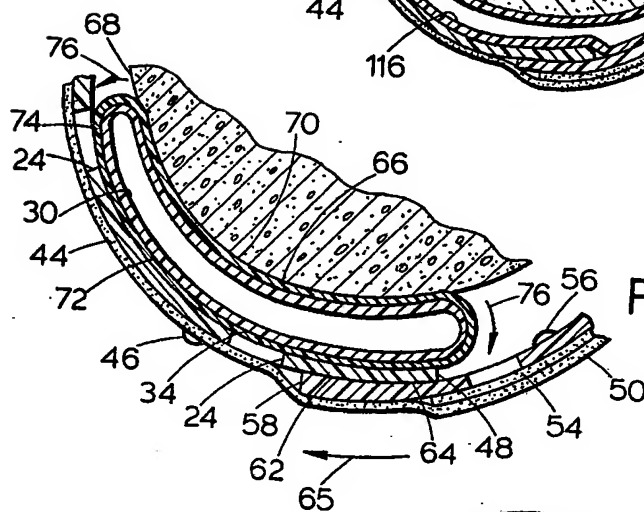
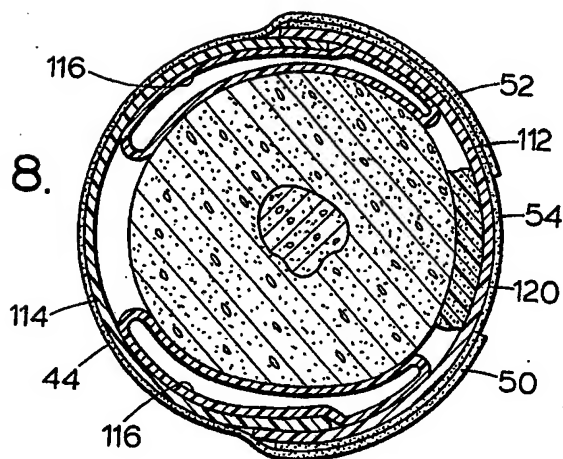
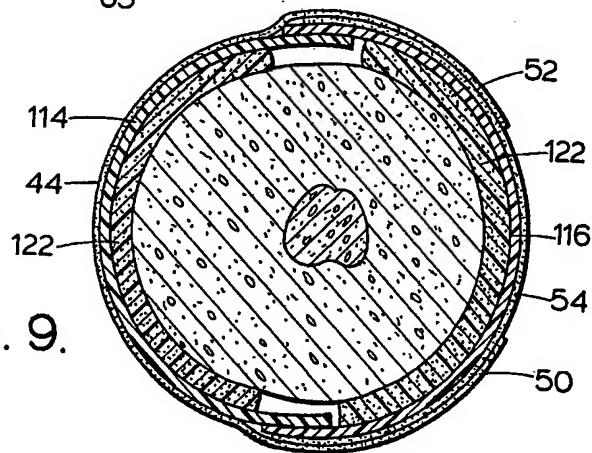


Fig. 6.

Fig. 9.



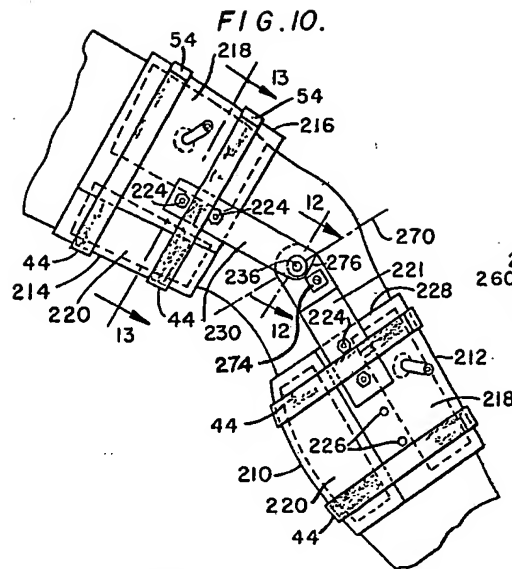


FIG. 12.

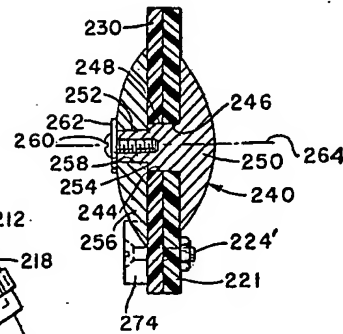


FIG. 11.

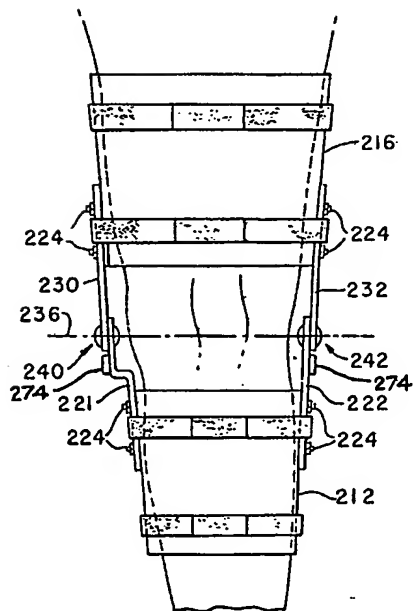
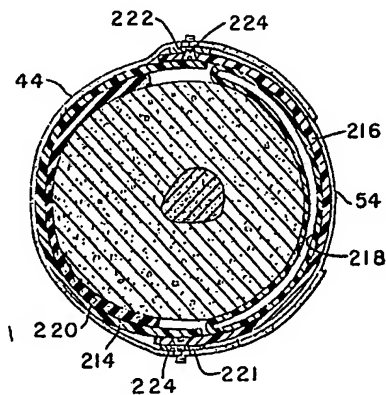


FIG. 13.



THIS PAGE BLANK (USPTO)